

# BIOSAFETY REGULATION

## **INTRODUCTION:**

The exploding population, especially in the developing countries like India needs to have a quantum jump in production of food and other agricultural products. Productivity has to be increased from all sources. This phenomenal increase of products needed for both humans and animals has to be achieved in an affordable, environmentally sustainable and ecologically sound manner. The new technologies and products needed for this purpose have to be safe to both humans and the entire ecosystem. Further success of a product is being seen and accepted by public at large as being so.

## **BIOSAFETY:**

Biosafety can be defined as the policies and procedure adopted to ensure the environmentally safe application of biotechnology. Regulation is a process by which the governments assure that the uncertainty and risks of new technology can be attained within manageable limits.

In India the biosafety regulation extends into three. They are as follows.

1. Regulation of biotech crops.
2. Regulation of bio-medicals.
3. Regulation of recombinant research activities.

## **ORGANISATIONS ASSOCIATED WITH CASE I :**

### **1. INSTITUTIONAL BIOSAFETY COMMITTEE (IBSC):**

A proposal to carry out any project involving genetic manipulation of microorganisms, plants and animals is discussed in IBSC, which is setup within that institution. The committee will constitute the following,

1. Head of the institution or nominee
2. Three or more scientist engaged in DNA work or molecular biology with an outside expert in the relevant discipline.
3. A member with medical qualifications – biosafety officer ( in case of pathogenic agents/large scale use).
4. One member nominated by DBT.

### **FUNCTIONS AND ACTIVITY OF IBSC :**

1. It should register with RCGM and should submit half yearly reports to them.
2. Review and clearance of project proposals falling under restricted category
3. Training personal on biosafety
4. Instituting health monitoring program and
5. adopting emergency plans

### **2. REVIEW COMMITTEE ON GENETIC MANIPULATION (RCGM):**

Following approval from IBSC, an application is prepared and submitted to the RCGM. It has the following composition.

1. Department of Biotechnology.
2. Indian Council of Medical Research.
3. Indian Council of Agricultural Research.
4. Council of scientific and industrial research.
5. Three experts in individual capacity.
6. Department of Science and Technology

The RCGM discusses the proposal and may recommend to the MEC for agronomic benefit evaluation.

**3. MONITORING CUM EVALUATION COMMITTEE (MEC):**

After detailed deliberations, MEC recommends the modified application back to the RCGM. MEC comprises of agricultural experts from various universities and institutes.

**4. STATE BIOTECHNOLOGY CO-ORDINATION COMMITTEE (SBCC):**

RCGM issues a Letter of Intent (LOI) to this institution seeking permission to conduct transgenic project and a copy is marked to the chief secretary of the state in which trial is planned. The SBCC is headed by the chief secretary of each of the Indian states and has the powers to grant consent to carry out transgenic research and inspect and investigate the activities related to GMOs in the respective states. The committee nominates representatives for such activities.

**5. DISTRICT LEVEL CO-ORDINATION COMMITTEE (DLCC):**

District collector heads this committee and it monitors the safety regulations associated with the project.

**6. NATIONAL BUREAU OF PLANT GENETIC RESOURCES (NBPGR):**

For import of small quantities of transgenic seeds RCGM recommends the issuance of an import clearance from DBT. Based on this the NBPGR, issues permit to import the transgenic seeds into the country. Presently there is no system for the export of transgenic seeds, even for research purposes.

**7. GENETIC ENGINEERING APPROVAL COMMITTEE (GEAC):**

GEAC will function under the Department of Environment (DOEn) as statutory body for review and approval of activities involving large scale use of genetically engineered organisms and their products in research and development, industrial production, environmental release and field applications.

**COMPOSITION OF THE COMMITTEE:**

1. Chairman – additional secretary, Department of Environment  
Co-chairmen- expert nominee (DBT)
2. Representatives of concerned agencies and departments.
  - Ministry of Industrial Development.
  - Department of Science and Technology
  - Department of Ocean technology
  - Department of Biotechnology
3. Expert members.

- Director General- Indian Council of Agricultural Research
- Director General- Indian Council of Medical Research
- Director General- Council of scientific and industrial research
- Director General- Health Services
- Plant protection advisor ( Ministry of agriculture)
- Chairman, Central Pollution Control Board.
- 3 outside experts in individual capacity.

The GEAC follows statutory rules and regulations laid down under environment protection act 1986.

### **IMPORTS AND SMALL SCALE FIELD TRIALS :**

Importing transgenic germplasm from foreign countries intended for research use is allowed. For this one must obtain import clearance from DBT. It takes about 18 weeks. However at the present time there is no system in place for the export of the transgenic seeds from India to any foreign country even for research purposes.

### **LARGE SCALE FIELD TRIALS :**

Following the completion of the biosafety studies are completed, DBT may issue biosafety studies clearance and may recommend the application to the GEAC for the further testing under large-scale trials. The entire process might take 35 weeks before final approval is granted.

### **COMMERCIAL RELEASE OF BIOTECH CROPS:**

Science no biotech crop has been released for commercial use in India the actual process is not known. However after large scale trials clearance from RCGM and GEAC is essential.

### **REGULATION FOR HEALTH CARE BIOTECH:**

A registration regime which would allow for quick registration and introduction of products in the health care segment would be beneficial for only the industry but for the country as a whole. The current activity chart for Biotechnology based drugs with regard to registration is as follows

### **REGULATION OF RECOMBINANT RESEARCH ACTIVITIES:**

It has the following institutions,

1. Recombinant DNA Advisory Committee (RDAC)
2. Institutional Biosafety Committee (IBSC)\*
3. Review Committee on Genetic Manipulation (RCGM)\*
4. Genetic Engineering Approval Committee (GEAC)\*

( \* - discussed already)

### **RECOMBINANT DNA ADVISORY COMMITTEE (RDAC) :**

The committee should take note of developments at national and international levels in biotechnology towards the current ness of the safety

regulation for India on recombinant research, use and applications. It would meet once in six months or sooner for this purpose.

**FUNCTIONS:**

1. To evolve long-term policy for research and development in rDNA research.
2. To formulate the safety guidelines for rDNA research
3. To recommend training program for research people and technicians to make them aware of the risks in rDNA research

**FROM THE ABOVE IT CAN BE SEEN THAT THE VARIOUS BOTTLE NECKS THAT EXISTS IN INDIA ARE:**

1. Time taken in transferring the application from one department to another.
2. No clear-cut guidelines on approval based on the importance and requirement in India as well as differentiation between those that are extensively marketed worldwide and for newer molecules that are developed or those in trial phase
3. The low frequency of the number of meetings of the GEAC committee meetings that are held during the year for approval of products in an area like biotechnology which is perceived to be as one of the most important factors for the delay of the entire process.